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BARNARD & BROWN  
306 STATE STREET, #220  
ITHACA, NEW YORK 14850

18N2/1209

ELLIS, J. EXAMINER

ART UNIT	PAPER NUMBER
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1807

17

DATE MAILED: 12/09/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 9/1/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4 and 6-21 are pending in the application.  
Of the above, claims 6-21 are withdrawn from consideration.
2. ☒ Claims 5 have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-4 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The finality of the previous office action is withdrawn in order to raise a new ground of rejection in light of newly discovered prior art.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

The specification teaches the construction of cDNA libraries and the differential screening of said libraries in order to isolate nucleotide sequences which encode cytokines. The specification discloses the isolation of a cDNA sequence known as 4-1BB and proposes, *inter alia*, that the protein encoded by the claimed cDNA sequence is a receptor protein. However, the specification fails to teach what ligand the instant protein is a receptor for, i.e., the utility of the receptor. The specification fails to disclose a utility for a cDNA sequence which encodes an unknown receptor for an unknown ligand.

The specification discloses that the protein encoded by the instant cDNA sequence is constitutively expressed in both brain cells and renal medullar cells, and can be induced in heart and spleen cells. In addition, the protein has an amino acid sequence which is similar to tumor necrosis factor and nerve growth factor, as well as a consensus sequence which can bind protein tyrosine kinase, a zinc finger motif, a nuclear protein domain, and a receptor domain. In view of all the data, the specification proposes several roles for the 4-1BB

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protein such as a neurotrophic factor (p. 43, lines 8-9), an accessory signaling molecule during T cell activation (p. 43, line 26), a cell surface receptor for T cells (p. 55, lines 12-14), etc.; however, the data fail to determine any actual function of the 4-1BB protein. Note Chalupny et al., Proc. Natl. Acad. Sci. USA 89:10360 (1992) (reference AS, Paper No. 5) teach that, in 1992 (4 years after the filing date of the parent application), the function of 4-1BB was still unknown and the role of 4-1BB needed to be characterized. See the abstract and p. 10364, last paragraph. In addition, Kwon et al., Cellular Immunology 121:414 (1989)(reference AR, Paper No. 6) teach that the nature of the 4-1BB gene product is difficult to predict. See p. 420, line 23. At best, the assays set forth in the specification merely indicate that the instant cDNA sequence encodes a cell surface protein, whose biological activity, i.e., utility, is yet unknown.

Case law has established that the utility of an invention may not be based on mere assertion, but rather must be definite and in a currently available form. In Brenner V. Manson, 383 U.S. 519, 148 U.S.P.Q. 689 (1966), the Supreme Court held:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point- where specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The Court further stated:

[t]hese arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process.

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Applicants cannot rely on the fact that homologous nucleotide sequences encode polypeptides that possess a particular biological activity in order to establish a utility for the instant composition. See Brenner v. Manson at 694. The statements in the specification that the instant cDNA sequence encodes a polypeptide which is "homologous" to so many different proteins with such diverse biological activities, does not establish a utility for the compositions recited in the claims. Furthermore, such statements affirm the Examiner's position that the data fail to provide convincing evidence that any utility has been reasonably established. In re Irons, 340 F.2d 974, 144 U.S.P.Q. 351 (C.C.P.A. 1965). In the instant case, applicant is merely proposing several avenues of research for those skilled in the art to pursue in order to determine for themselves a utility for the claimed compositions.

Applicant argues that (i) the specification clearly teaches the function of 4-1BB, (ii) 4-1BB is an inducible "receptor-like" protein expressed in many different cell types, and (iii) cross-linking of 4-1BB on anti-CD3-stimulated T cells results in enhancement of T cell proliferation. Applicant cites several regions of the specification as support for these arguments. In addition, applicant urges that it is not necessary to know the exact *in vivo* role of 4-1BB, because the *in vitro* effect on T cells is important to "any problem" in an organism that results in a low T-cell count, such as AIDS, or in culturing cells. These arguments and the referenced regions of the specification have been carefully considered, but are not persuasive. As set forth in the previous office action (Paper No. 11), the descriptive characteristics in the referenced regions of the specification are merely initial experimental

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steps performed in order to ascertain what is the actual biological role, or utility, of 4-1BB. These characteristics do not disclose the (i) biological activity of 4-1BB, or (ii) how to use 4-1BB. For example, p. 25, lines 10-13 of the specification merely disclose that 4-1BB transcripts, i.e., mRNA, was induced by ConA, and suppressed by cyclosporin A, in three cell types. This statement does not disclose a utility for the 4-1BB protein. In fact, from these data the specification observes (p. 25, lines 16-18) that "the expression pattern of 4-1BB resembles those of lymphokine mRNAs while the sequence appears consistent with those of receptor proteins." These two suggested utilities are mutually exclusive, i.e., 4-1BB can not possibly be both a lymphokine and a receptor protein. In addition, Kwon et al., Cellular Immunology 121:414 (1989) (reference AR, Paper No. 6) concur with the teachings of the specification that the mitogen data do not demonstrate a utility for the instant cDNA sequence, or the protein which it encodes. Note p. 420, paragraph 2 concludes that "the nature of the 4-1BB gene product is difficult to predict". Accordingly, the data from these initial experiments merely provide descriptive characteristics, but fail to even determine whether 4-1BB encodes a lymphokine (soluble proteins secreted by lymphocytes, T and B cells, which stimulate other cells in immune system, e.g., macrophages, B-cells, *etc.*, when they bind to their respective cell surface receptor) or a receptor (a cell surface molecule which binds specifically to proteins or peptides in the fluid phase).

Further, pp. 39-43 of the specification teach the inducibility of 4-1BB mRNA in spleen, brain, and kidney cells and describe the general distribution of the 4-1BB protein in

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brain cells. The distribution pattern, i.e., cellular location, of a protein does not reveal the activity, or utility for said protein. From the distribution pattern of 4-1BB in brain cells, the specification proposes that it [4-1BB] may be a receptor or nerve terminal (p. 42, lines 20-21), or even a neurotrophic factor (a protein which supports the survival of neurons)(p. 43, lines 7-9). Not only are these three functions completely distinct from the two proposed on p. 25, i.e., a lymphokine or a lymphokine receptor, but these proposals of such divergent functions clearly indicate that a utility for the 4-1BB protein has not been ascertained.

Applicant's allegation that the teaching on p. 43 of the specification that the cross-linking of 4-1BB on stimulated T-cells with the monoclonal antibody 53A2 results in enhancement of T-cell proliferation establishes a utility for the claimed cDNA sequence does not address the claimed invention. As set forth above, the monoclonal antibody is a patentably distinct invention. Note the restriction requirement set forth in Paper No. 8. Applicant's suggestion that the claimed 4-1BB cDNA sequence can be used to make the 4-1BB protein which in turn can be used to immunize mice to make monoclonal antibodies which then can be used to enhance the proliferation of anti-CD3-stimulated T cells is a bit strained. Furthermore, the specification teaches that the monoclonal antibody cross-linking experiment "*suggests that 4-1BB may function as an accessory signaling molecule during T cell activation*". Note p. 43, lines 25-26. [Emphasis added]. Accordingly, these data do not establish any utility for the claimed cDNA sequence, but merely provide additional descriptive characteristics of the protein, and a proposed area of research.

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Finally, the statement that the enhancement of T cell proliferation (when using the monoclonal antibody, Brief, p. 4., line 16) is important to any problem in an organism that results in a low T-cell count, such as AIDS, or in culturing cells is merely the argument of counsel and is not supported by evidence or declarations by those skilled in the art.

Counsel's arguments cannot take the place of objective evidence. See In re Langer, 503 F.2d 1380, 183 U.S.P.Q. 288 (C.C.P.A. 1974); In re Payne, 606 F.2d 303, 203 U.S.P.Q. 245 (C.C.P.A. 1979). Not only is it not clear what applicant intends by "any problem in an organism that results in a low T-cell count", but the single example provided, i.e., AIDS, is not a disease of mice. The instant cDNA sequence was derived from mouse cells, not humans. A cognate human molecule has not been identified. Further, with respect to the proliferation of CD3-stimulated T cells *in vitro* cultures using the monoclonal antibody, 53A2, again, this is merely an observation, or phenomenon, which occurs in the presence of the monoclonal antibody, but it fails to disclose a utility, or actual function of the claimed 4-1BB cDNA and the protein which it encodes. In addition, with respect to the assertion that the monoclonal antibody treatment is important in the culturing of cells, applicant has failed to specify the type of cell cultures, or what effect the monoclonal antibody (not, the claimed invention) will have on cultured cells.

Applicant also argues that 4-1BB has two other mutually exclusive utilities, i.e., to induce or suppress B-cell proliferation. Applicant urges that p. 5, lines 10-21 support this position wherein the specification alleges that this characteristic has a practical application in



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organ transplants. Finally, applicant alleges that he has demonstrated "how 4-1BB, the monoclonal antibody can be used in a utilitarian way". This argument and the referenced region of the specification have been carefully considered, but are not persuasive for several reasons. First, presumably appellant (and the specification) are referring to the application of the suppression of B cell proliferation in human organ transplants, and not mice. The instant cDNA sequence encodes a mouse protein and the cognate human molecule has not been identified. Each individual animal possesses its own characteristic set of histocompatibility antigens, i.e., cell membrane proteins which provoke an immune response when an organ is transplanted into a genetically different individual of the same species. Therefore, because the genes encoding the human major histocompatibility complex are different from those of the mouse, the instant cDNA sequences do not encode proteins which are capable of playing a role in human organ transplant. Second, to date the interaction of B cells during organ transplant has not been established and applicant has merely proposed a theory as to a possible mode of interaction. What is known in the art is that there is a strong T cell component to the immune response that occurs during organ transplant, i.e., this is a T cell dependent response. Applicant's model has no T cell component to it. Third, the specification teaches several assays which attempt to characterize the function of the 4-1BB protein in B cells. See pp. 67-80. The conclusion from these experiments are set forth on p. 80, lines 23-27, clearly indicate that the effect of 4-1BB on B cells is unknown. The specification discloses that "future experiments will focus on characterization of the 4-1BB



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binding site(s) and determining if 4-1BB is involved in thymus dependent-B-cell proliferation and differentiation". Accordingly, the alleged utility of 4-1BB in either the induction or suppression of B cell proliferation has not been reasonably established.

The Court has held in Brenner v. Manson, 383 U.S. 519, 148 U.S.P.Q. 689 (1966), that the utility of an invention must be in a definite and currently available form. Products which have no known use or which are useful only as the object of scientific research are not useful within the meaning of 35 U.S.C. § 101. The Court further held that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Brenner v. Manson, 148 U.S.P.Q. at 696. In the instant case, the specification fails to disclose a utility for 4-1BB other than as an object of further research. Further, even as late as 1992, Chalupny et al., *supra*, (reference AS, Paper No. 5) teach that the function of the 4-1BB protein was still unknown. The mere disclosure of the nucleotide/amino acid sequence of a protein, and preliminary experiments suggesting avenues of future research, fail to provide substantive evidence that the utility of the instant DNA sequence, and the protein, which it encodes has been reasonably established.

Finally, applicant's argument directed to the monoclonal antibody is unclear. Presumably, applicant intends that it has been demonstrated that the monoclonal antibody to 4-1BB has a utility. This argument does not address the claimed invention. Applicant did not elect the claims directed to the monoclonal antibody in the restriction requirement set forth in Paper No. 8.

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure.

The specification teaches the isolation and characterization of the nucleotide/amino acid sequence of the protein 4-1BB. However, the specification fails to provide an adequate written description, or teachings of enablement, of fragments and derivatives of the nucleotide sequence encoding 4-1BB which are capable of being used as a probe to isolate DNA sequences encoding proteins which are "similar" to the protein 4-1BB. First, the specification fails to provide an adequate written description as to which DNA sequences are to be isolated with the "probe". That is, the specification fails to disclose what constitutes a protein which is "similar" to the protein 4-1BB. Are proteins which share some, unspecified, degree of residue identity with the amino acid sequence of the instant protein similar? Proteins which have the same biological properties? Both? Or does applicant intend any nucleotide sequence which hybridizes to the instant cDNA sequence under any experimental conditions? The mere hybridization of a "fragment" derived from the nucleotide sequence set forth in Figures 2A and 2B does not ensure the isolation of a known product with a known biological activity,

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especially in view of the unknown biological role of the instant 4-1BB protein. The specification fails to teach whether protein 4-1BB is, in fact, a receptor, or for what ligand it is a receptor for. Further, if 4-1BB is a receptor, the specification fails to disclose whether it is a member of a family of receptor proteins, or the degree of residue identity among the family members. Accordingly, the specification fails to enable one skilled in the art to determine the hybridization conditions to employ for the identification and isolation of proteins which are "similar" to the instant protein. Second, the specification fails to provide an adequate written description, or a single working example, of nucleotide sequences which constitute a "derivative" of the 4-1BB nucleotide sequence. That is, the specification fails to provide an adequate written description, or teachings of enablement, as to the composition of 4-1BB "analogs". The specification fails to teach any methods of making a 4-1BB analog which has the same biological properties of the instant protein. In order to construct a biologically active analog, the specification must provide teachings as to what are the biological properties of the protein, what portions of the protein are essential for biological activity, and provide guidelines as to what alterations can be made to the amino acid sequence that would not affect its biological properties. The protein 4-1BB is approximately 250 amino acids in length, and there are 20 different amino acids which exist in nature. Accordingly, approximately 5,000 different 4-1BB analogs can be made by substituting only a single amino acid position, and over one million different analogs can be made by substituting three amino acids. It is well established that some amount of experimentation does not constitute a lack of

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enablement; however, the amount of experimentation must not be unduly extensive. See In re Fisher, 427 F.2d 833, 166 U.S.P.Q. 18 (C.C.P.A. 1970). In the instant case, the specification fails to teach, or provide guidelines for, one skilled in the art to make biologically active analogs which are effective as probes for "similar" proteins. Accordingly, one skilled in the art cannot make and use the invention as claimed. See Amgen v. Chugai Pharmaceutical Co. Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

Third, the specification fails to provide an adequate written description as to what regions of the 4-1BB sequences to employ as probes. Because it is not clear what nucleotide sequences are to be identified and isolated using fragments and "derivatives" of 4-1BB, it is not clear what regions of the instant cDNA to employ as a probe.

Finally, the specification fails to provide any teachings as to how to use the protein encoded by the instant cDNA sequence. For example, assuming arguendo, the 4-1BB is a receptor protein, one skilled in the art must know which ligand binds to the receptor in order to use it. Given the lack of any teachings or guidelines in the specification, and the total unpredictability of the nature of the ligand which binds to the instant "receptor-like" protein, one skilled in the art could not use the claimed invention, absent undue experimentation. See Ex parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. & Inter. 1986); Ex parte Sudilovsky, 21 U.S.P.Q.2d 1702 (Bd. Pat. App. & Inter 1991).

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Claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite in the recitation of fragments and derivatives of the 4-1BB cDNA which can be used as probes. It is not clear which nucleotide sequences applicant intends. The claim is further vague and indefinite in the recitation of proteins which are "similar" to the 4-1BB protein. It is not clear which nucleotide/amino acid sequences applicant intends.

Applicant argues that (i) the specification discloses that the probes must be capable of being used to isolate DNA sequences encoding "similar" proteins, (ii) the term "similar" is not vague and indefinite, (iii) DNA probes are not used in activity assays, (iv) references discussing the "intercrine  $\beta$ -superfamily" [sic, subfamily?] are referred to in the specification and that conserved sequences fragments are identified which would make the most likely candidates for probes, and (iv) many modifications can be made to the instant DNA sequence without affecting the amino acid sequence. These arguments have been considered, but are not persuasive for several reasons.

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First, claim 4 is directed to fragments and derivatives of the cDNA sequences shown in Figures 2a and 2b (claim 2). An intended use does not place a further limitation on a claim. The fragments and derivatives of the cDNA set forth in the referenced figures can be used for any purpose, e.g., primers, expression of epitopes, *etc.* Accordingly, applicant's argument that the probes must be capable of isolating similar sequences does not address a limitation present in the claims. Consequently, it does not constitute a functional limitation.

Second, applicant's argument that the term "similar" is not vague and indefinite because a "DNA probe can not by [sic, be?] used to determine anything other than homology" does not address a limitation present in claim or constitute a functional limitation. "Homology" has the precise meaning in biology of "having a common evolutionary origin". See Reeck et al., *Cell* 50:667(1987) and Lewin, *Science*, 237:1570 (1987). Reeck et al. further teach that "evidence for evolutionary homology should be explicitly laid out, making it clear that the proposed relationship is based on the level of observed similarity, the statistical significance of similarity, and possibly other lines of reasoning". Note p. 667, col. 2, third complete paragraph. Therefore, the assertion that "DNA probes *determine homology*" (Emphasis added) is not only unclear, but, absent evidence, or declarations by those skilled in the art, it [the assertion] is merely an unsubstantiated argument of counsel. See In re Langer, 503 F.2d 1380, 183 U.S.P.Q. 288 (C.C.P.A. 1974); In re Payne, 203 U.S.P.Q. 245. Further, sequence identity is not a functional limitation, but a structural limitation. A functional limitation is present in claims when they are directed to DNA

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sequences which hybridize to a DNA probe *and* which encode *a protein with the same activity or biological properties* as the protein encoded by the DNA sequence from which the probe was derived. In the instant case, claim 4 is vague and indefinite because the claim fails to specify whether "proteins similar to the receptor protein" are similar in a structural (amino acid composition) or functional (same biological properties) sense. Given that the function of 4-1BB has not been disclosed, the specification also fails to enable one skilled in the art to determine what constitutes a "similar" protein. Further, the specification fails to provide an adequate written description of cDNA sequences which are "homologous" to the instant cDNA.

Third, applicant's remarks that DNA probes are not used in activity assays for lymphokines are unclear and, accordingly, can not be addressed at this time.

Fourth, the "intercrine" family consists of DNA sequences which encode cytokines (soluble protein secreted by various cells of the immune system; not receptor proteins) which are basic, heparin-binding proteins and have proinflammatory and reparative activities. See Oppenheim et al., Annu. Rev. Immunol. 9:617 (1991) p. 618, col. 1. (Oppenheim et al. is reference BB, Paper No. 7). The cytokine genes which are located on human chromosome 17, e.g., LD-78, ACT-2, RANTES, and macrophage attractant and activating factor-MCAF, are in the intercrine  $\beta$  subfamily. Oppenheim, *supra*, the sentence bridging p. 618 and 619. The specification fails to teach that the instant 4-1BB encodes a cytokine, encodes a cytokine whose gene maps to human chromosome 17, or is a member of the



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intercrine  $\beta$  subfamily. Accordingly, this argument is merely the argument of counsel and is unsupported by evidence or declarations by those skilled in the art. See In re Langer, *supra*; In re Payne, *supra*.

Fifth, with respect to applicant's assertion that p. 38, line 28- p. 39, line 16 and Figure 17 identifies the most likely candidates for probes is incorrect. The referenced regions of the specification teach that 4-1BB protein shares some residue identity with a small region of a *Drosophila* (an insect, fruit fly) and a *Dictyostelium* (slime mold) protein. The specification further teaches that the "conserved pattern *suggests* that these amino acids are functionally important". Page 39, lines 15-16. [Emphasis added]. The specification does **not** teach that these regions of the instant cDNA sequence which encode amino acids sequences which share residue identity with insect and slime mold proteins are useful as probes for isolating mouse (or human) lymphokines or receptor proteins.

Sixth, contrary to applicant's assertion, the term "derivatives" encompasses more than silent codon changes, but it also encompasses DNA sequences which encode analogs of the protein encoded by the instant sequence. As set forth above, given that the biological activity, or function, of the protein encoded by the instant nucleotide sequence has not been characterized, the specification fails to enable one skilled in the art to make biologically active analogs which possess the same properties of the 4-1BB protein. See Amgen v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

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### New Ground of Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kwon et al., Proc. Natl. Acad. Sci. U.S.A. 86:1963 (1989), reference BO, Paper No. 7.

Kwon et al. teach a cDNA sequence which encodes the receptor protein 4-1BB. Note Figure 2.

The instant application is a C-I-P of Serial No. 07/922,966, filed July 30, 1992 and of 07/267,577 filed November 7, 1988. The parent application, 07/267,577 teaches that 4-1BB is a novel sequence of unknown function. Note p. 2, lines 40-42. In addition, in contrast to the instant application which teaches that 4-1BB encodes a protein receptor, the parent application *suggests* that instant cDNA sequence encodes a **lymphokine**, a soluble the protein secreted by a lymphocyte. Accordingly, since the parent application fails to teach the utility, or provide an enabling disclosure, i.e., how to use the 4-1BB cDNA sequence, applicant is not entitled to a 1988 priority date. Therefore, the Kwon et al. reference is applicable as prior art. See In re Spada, 911 F.2d 705, 15 U.S.P.Q.2d 1655 (Fed. Cir. 1990); In re Schoenwald, 964 F.2d 1122, 22 U.S.P.Q.2d 1671 (Fed. Cir. 1992).

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In view of the rejection under 35 U.S.C. § 102(b), *supra*, the rejection set forth in the previous office action under 35 U.S.C. § 103 is deemed superfluous and is herein withdrawn. Accordingly, it is not necessary to address applicant's arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Ellis whose telephone number is (703) 308-3990.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOAN ELLIS  
PRIMARY EXAMINER  
GROUP 180

J. Ellis, Ph.D.  
November 23, 1994